

Frequently Asked Questions for Biosample Access

Q: When do I need to use the X01 (PAR 14-340) to access biosamples?

A: Whenever you want to access biosamples from the [NINDS Parkinson's Disease Biomarkers Program \(PDBP\)](#), the [Michael J. Fox Foundation \(MJFF\) sponsored LRRK2 Cohort](#), [BioFIND](#), [DATATOP](#), and [24-hour Biofluid Sampling cohorts](#), the [NINDS National Brain and Tissue Repository for Parkinson's Disease and related disorders](#) at the Banner Sun Health Research Institute, or the [Harvard Biomarker Study for Parkinson's Disease Biomarker discovery](#). Please refer to the slide set from the recent webinar on Parkinson's Disease Biosample Resources and Access for additional information on the resources available and the procedure for requesting biosamples.

Q: What cohorts and biosamples can be accessed through the X01 request?

A: The cohorts and associated biosamples that can be accessed through the X01 request are outlined on this [website](#) and include the NINDS Parkinson's Disease Biomarkers Program (PDBP), the Michael J. Fox Foundation (MJFF) sponsored cohorts including the LRRK2 Cohort, BioFIND, DATATOP, and 24-hour Biofluid Sampling cohorts, the NINDS National Brain and Tissue Repository for Parkinson's Disease and related disorders at the Banner Sun Health Research Institute, and the Harvard Biomarker Study.

Q: How long will it take to find out about approval for biosample access?

A: The Biosample Resource Access Committee (BRAC) meets 6 times a year. Specific submission time windows and review dates for 2015 are:

- i. Submissions between March 16 - July 15, 2015
Review date: July 30, 2015
- ii. Submissions between July 16 - September 15, 2015
Review date: October 1, 2015
- iii. Submissions between September 16 - November 15, 2015
Review date: December 3, 2015

Q: What are the criteria used by the BRAC for approval of a sample request?

Briefly, the BRAC uses the following simple guidelines when considering a sample request:

- Is there sufficient evidence supporting the likelihood of this study identifying novel biomarkers?
- Does the rationale of the study justify use of the requested samples?
- Do the investigators have the expertise, personnel and the institutional resources to achieve the goals of the proposal?
- Is the number of samples requested reasonable and sufficiently powered to achieve statistical significance?

- Is there a data sharing plan?

Q: Who are the members of the BRAC?

BRAC membership is listed [here](#). Representatives from the projects which collected samples as well as scientific experts are included. Conflict of interest is managed per the NIH Study Section [Conflict of Interest guidelines](#).

Q: What if I do not currently have funding for biomarker research?

A: You can apply for biosample access to support an upcoming grant application. If your request is approved by the PD BRAC, then a provisional letter of approval will be provided for your grant application. If you require a limited number of biosamples or tissue samples to generate pilot data for a grant application, then you can apply through the X01 mechanism.

Q: What is the intended usage of the biosamples available under the X01 request?

A: Overall the intended use of the biosamples represented by the various cohorts under the X01 mechanism is for Parkinson's Disease biomarker discovery, optimization and replication.

Q: Who determines whether access is granted for biosample requests?

A: An NIH (NINDS) study section specifically setup to review X01 applications received under PAR 14-340 will be convened 6 times a year and coordinated by NINDS.

Q: Can non-US based investigators request biosamples?

A: Yes, non-US based investigators are encouraged to apply.

Q: What if the organization applying cannot apply via eraCommons?

A: All potential applicants are STRONGLY encouraged to apply via eraCommons. Instructions for setting up an eraCommons account can be found [here](#). If the foreign institute or company does not have the information (eg a DUNS number or SAM registration) required to setup an account in the NIH eRA Commons, an X01 application can be submitted via the NINDS-PD-BRAC@ninds.nih.gov. Please email [NINDS BRAC](#) for further instructions.

Q: Can industry and biotech companies request biosamples?

A: **Yes**, industry and biotech companies are encouraged to apply for biosample and tissue access.

Q: What if I only need a few samples for a pilot study?

A: Pilot studies are supported through the X01 mechanism.

Q: Are there any additional considerations once biosample access is approved by the PD BRAC?

A: Each cohort may have additional documentation requirements such as a Biospecimen Use Agreement, Data Use Agreement, and/or Publication Policy, which must be acknowledged and received before samples are sent to the requestor. Specific contact information for each cohort represented under the PD BRAC can be found at this [website](#).

Q. How can I find out more information about the clinical assessments and biological data available for biosamples from the NINDS PDBP cohort?

A. The best way to access the clinical and biological data available for PDBP biosamples to is [request an account](#) with the PDBP data management resource (DMR).